

REMARKS/ARGUMENTS

This is a preliminary amendment in a RCE application. The Office Action mailed February 14, 2007 has been carefully reviewed. Reconsideration of this application, as amended and in view of the following remarks, is respectfully requested. The claims originally in the application were claims 1-35. Claims 2, 3, 22, 23, 24, 26, 27, 28, 29, 30, and 33 have been cancelled. The claims presented for examination are: claims 1, 4-21, 25, 31, 34, and 35.

35 USC §102 Rejection – Linden et al

In the Office Action mailed February 14, 2007 on pages 2-6, claims 1-4, 6, 8-11, 16-26, 28, and 30-35 were rejected under 35 USC §102(b) as being anticipated by the Linden et al reference (US Patent No. 5,634,936).

Applicants have amended the claims and believe the invention claimed in the amended claims is not anticipated by the Linden et al reference. The invention claimed in Applicants' amended claims is an apparatus, system, and method for closure of a physical anomaly in a vascular wall. Applicants' claimed apparatus, system, and method includes many claim elements that are not disclosed by the Linden et al reference. Some of Applicants' claim elements that are not disclosed by the Linden et al reference include: a closure body, said closure body made of a shape memory polymer (SMP) foam, said shape memory polymer (SMP) foam having at least one hard segment and one soft segment wherein said hard segment is formed at a temperature above T_{trans} and said soft segment is formed at a temperature below T_{trans} , said shape memory polymer (SMP) foam being formed into a primary shape, compressed into a reduced secondary stable shape, then controllably actuated so that it recovers its primary shape, and a delivery device adapted to received said closure body made of a shape memory polymer (SMP) foam with said shape memory polymer (SMP)

foam being compressed into said reduced secondary stable shape in said delivery device, said delivery device adapted to deploy said closure body into the physical anomaly in the vascular wall, wherein said shape memory polymer (SMP) foam of said closure body in said reduced secondary stable shape is configured for positioning said closure body within the physical anomaly in the vascular wall, and wherein said shape memory polymer (SMP) foam is controllably actuated so that it recovers its primary shape with said primary shape configured to close said anomaly.

The standard for a 35 USC §102 rejection is stated in *RCA Corp. v. Applied Digital Systems, Inc*, 221PQ 385, 388 (d. Cir. 1984) "Anticipation is established only when a single prior art reference discloses, either expressly or under principles of inherency, each and every element of a claimed invention." Since Applicants' claim elements described above are not found in the Linden et al reference, the Linden et al reference does not support a 35 USC §102(b) rejection of Applicants' amended claims and the rejection should be withdrawn.

35 USC §102 Rejection –Kamiya et al

In the Office Action mailed February 14, 2007 on pages 6-8, claims 1, 19, and 32 were rejected under 35 USC §102(b) as being anticipated by the Kamiya et al reference (US Patent No. 5,634,936).

Applicants have amended claims 1, 19, and 32 and believe the invention claimed in amended claims 1, 19, and 32 is not anticipated by the Kamiya et al reference. The invention claimed in Applicants' amended claims 1, 19, and 32 is an apparatus, system, and method for closure of a physical anomaly in a vascular wall. Applicants' claimed apparatus, system, and method includes many claim elements that are not disclosed by the Kamiya et al reference. Some of Applicants' claim elements that are not disclosed by the Kamiya et al reference include: a closure body, said closure body made of a shape memory polymer

(SMP) foam, said shape memory polymer (SMP) foam having at least one hard segment and one soft segment wherein said hard segment is formed at a temperature above T_{trans} and said soft segment is formed at a temperature below T_{trans} , said shape memory polymer (SMP) foam being formed into a primary shape, compressed into a reduced secondary stable shape, then controllably actuated so that it recovers its primary shape, and a delivery device adapted to receive said closure body made of a shape memory polymer (SMP) foam with said shape memory polymer (SMP) foam being compressed into said reduced secondary stable shape in said delivery device, said delivery device adapted to deploy said closure body into the physical anomaly in the vascular wall, wherein said shape memory polymer (SMP) foam of said closure body in said reduced secondary stable shape is configured for positioning said closure body within the physical anomaly in the vascular wall, and wherein said shape memory polymer (SMP) foam is controllably actuated so that it recovers its primary shape with said primary shape configured to close said anomaly.

The standard for a 35 USC §102 rejection is stated in *RCA Corp. v. Applied Digital Systems, Inc.*, 221PQ 385, 388 (d. Cir. 1984) "Anticipation is established only when a single prior art reference discloses, either expressly or under principles of inherency, each and every element of a claimed invention." Since Applicants' claim elements described above are not found in the Kamiya et al reference, the Kamiya et al reference does not support a 35 USC §102(b) rejection of Applicants' amended claims 1, 19, and 32 and the rejection should be withdrawn.

35 USC §103 Rejection – Linden et al in View of Michlitsch

In the Office Action mailed February 14, 2007 on pages 8 and 9, claims 12-15 and 25 were rejected under 35 USC §103(a) as being unpatentable over the

Linden et al reference (US Patent No. 5,634,936) in view of the Michlitsch reference (US 2006/0155330).

Applicants have amended the claims and believe the invention claimed in the amended claims is patentable over the Linden et al and Michlitsch references. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966) that are applied for establishing a background for determining obviousness under 35 USC §103 include "Ascertaining the differences between the prior art and the claims at issue." Differences between the Linden/Michlitsch Li references and Applicants' claimed invention includes the fact that the many claim elements of Applicants' amended claims 12-15 and 25 are not found in the Linden et al reference or the Michlitsch reference.

The invention claimed in Applicants' amended claims 12-15 and 25 is an apparatus and method for closure of a physical anomaly in a vascular wall. Some of Applicants' claim elements of amended claims 12-15 and 25 that are not disclosed by the Linden reference or the Michlitsch reference include: a closure body, said closure body made of a shape memory polymer (SMP) foam, said shape memory polymer (SMP) foam having at least one hard segment and one soft segment wherein said hard segment is formed at a temperature above T_{trans} and said soft segment is formed at a temperature below T_{trans} , said shape memory polymer (SMP) foam being formed into a primary shape, compressed into a reduced secondary stable shape, then controllably actuated so that it recovers its primary shape, and a delivery device adapted to received said closure body made of a shape memory polymer (SMP) foam with said shape memory polymer (SMP) foam being compressed into said reduced secondary stable shape in said delivery device, said delivery device adapted to deploy said closure body into the physical anomaly in the vascular wall, wherein said shape memory polymer (SMP) foam of said closure body in said reduced secondary stable shape is

configured for positioning said closure body within the physical anomaly in the vascular wall, and wherein said shape memory polymer (SMP) foam is controllably actuated so that it recovers its primary shape with said primary shape configured to close said anomaly.

The provisions of M.P.E.P. Section 2142 require: (1) there must be some suggestion or motivation, either in the reference themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teaching, (2) there must be a reasonable expectation of success with the combined references system, and (3) that the prior art reference (or reference when combined) must teach or suggest all the claim limitations. The Linden reference and the Michlitsch reference and any combination of the two references fail to meet the three requirements of M.P.E.P. Section 2142. Accordingly the rejection of Applicant's claims 12-15 and 25 is not appropriate and the rejection should be withdrawn.

35 USC §103 Rejection – Linden et al in View of Li

In the Office Action mailed February 14, 2007 on page 9, claims 5, 7, 27, and 29 were rejected under 35 USC §103(a) as being unpatentable over the Linden et al reference (US Patent No. 5,634,936) in view of the Li reference (US 5,571,181).

Applicants have cancelled claims 27 and 29 and amended claim 5 and 7. Applicants believe the invention claimed in amended claims 5 and 7 is patentable over the Linden et al and Li references. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966) that are applied for establishing a background for determining obviousness under 35 USC §103 include "Ascertaining the differences between the prior art and the claims at issue." Differences between the Linden/Li references and Applicants' claimed

invention includes the fact that the many claim elements of Applicants' amended claims 5 and 7 are not found in the Linden reference or the Li reference.

The invention claimed in Applicants' amended claims 5 and 7 is an apparatus for closure of a physical anomaly in a vascular wall. Some of Applicants' claim elements of amended claims 5 and 7 that are not disclosed by the Linden reference or the Li reference include: a closure body, said closure body made of a shape memory polymer (SMP) foam, said shape memory polymer (SMP) foam having at least one hard segment and one soft segment wherein said hard segment is formed at a temperature above T_{trans} and said soft segment is formed at a temperature below T_{trans} , said shape memory polymer (SMP) foam being formed into a primary shape, compressed into a reduced secondary stable shape, then controllably actuated so that it recovers its primary shape, and a delivery device adapted to received said closure body made of a shape memory polymer (SMP) foam with said shape memory polymer (SMP) foam being compressed into said reduced secondary stable shape in said delivery device, said delivery device adapted to deploy said closure body into the physical anomaly in the vascular wall, wherein said shape memory polymer (SMP) foam of said closure body in said reduced secondary stable shape is configured for positioning said closure body within the physical anomaly in the vascular wall, and wherein said shape memory polymer (SMP) foam is controllably actuated so that it recovers its primary shape with said primary shape configured to close said anomaly.

The provisions of M.P.E.P. Section 2142 require: (1) there must be some suggestion or motivation, either in the reference themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teaching, (2) there must be a reasonable expectation of success with the combined references system, and (3) that the prior art reference

(or reference when combined) must teach or suggest all the claim limitations. The Linden reference and the Li reference and any combination of the two references fail to meet the three requirements of M.P.E.P. Section 2142. Accordingly the rejection of Applicant's claims 5 and 7 is not appropriate and the rejection should be withdrawn.

35 USC §103 Rejection – Linden et al in View of Langer et al

In the Office Action mailed February 14, 2007 on pages 9 and 10, claims 1-4, 6, 8-11, 16-26, 28, and 30-35 were rejected under 35 USC §103(a) as being unpatentable over the Linden et al reference (US Patent No. 5,634,936) in view of the Langer et al reference (US 6,388,043).

Applicants have amended claims 1-4, 6, 8-11, 16-26, 28, and 30-35. Applicants believe the invention claimed in amended claims 1-4, 6, 8-11, 16-26, 28, and 30-35 is patentable over the Linden et al and Langer et al references. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966) that are applied for establishing a background for determining obviousness under 35 USC §103 include "Ascertaining the differences between the prior art and the claims at issue." Differences between the Linden/Langer references and Applicants' claimed invention includes the fact that the many claim elements of Applicants' amended claims 1-4, 6, 8-11, 16-26, 28, and 30-35 are not found in the Linden et al reference or the Langer et al reference.

The invention claimed in Applicants' amended claims 1-4, 6, 8-11, 16-26, 28, and 30-35 is an apparatus, system, and method for closure of a physical anomaly in a vascular wall. Some of Applicants' claim elements of amended claims 1-4, 6, 8-11, 16-26, 28, and 30-35 that are not disclosed by the Linden et al reference or the Langer et al reference include: a closure body, said closure body made of a shape memory polymer (SMP) foam, said shape memory polymer (SMP) foam having at least one hard segment and one soft segment wherein said

hard segment is formed at a temperature above T_{trans} and said soft segment is formed at a temperature below T_{trans} , said shape memory polymer (SMP) foam being formed into a primary shape, compressed into a reduced secondary stable shape, then controllably actuated so that it recovers its primary shape, and a delivery device adapted to received said closure body made of a shape memory polymer (SMP) foam with said shape memory polymer (SMP) foam being compressed into said reduced secondary stable shape in said delivery device, said delivery device adapted to deploy said closure body into the physical anomaly in the vascular wall, wherein said shape memory polymer (SMP) foam of said closure body in said reduced secondary stable shape is configured for positioning said closure body within the physical anomaly in the vascular wall, and wherein said shape memory polymer (SMP) foam is controllably actuated so that it recovers its primary shape with said primary shape configured to close said anomaly.

The provisions of M.P.E.P. Section 2142 require: (1) there must be some suggestion or motivation, either in the reference themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teaching, (2) there must be a reasonable expectation of success with the combined references system, and (3) that the prior art reference (or reference when combined) must teach or suggest all the claim limitations. The Linden et al reference and the Langer et al reference and any combination of the two references fail to meet the three requirements of M.P.E.P. Section 2142. Accordingly the rejection of Applicant's claims 1-4, 6, 8-11, 16-26, 28, and 30-35 is not appropriate and the rejection should be withdrawn.

35 USC §103 Rejection – Linden and Langer in View of Michlitsch

In the Office Action mailed February 14, 2007 on page 10, claims 12-15 and 25 were rejected under 35 USC §103(a) as being unpatentable over the Linden et

al reference (US Patent No. 5,634,936) and Langer et al reference (6,388,043) in view of the Michlitsch reference (US 2006/0155330).

Applicants have amended the claims and believe the invention claimed in the amended claims is patentable over the Linden and Langer and Michlitsch references. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966) that are applied for establishing a background for determining obviousness under 35 USC §103 include "Ascertaining the differences between the prior art and the claims at issue." Differences between the Linden and Langer/Michlitsch Li references and Applicants' claimed invention includes the fact that the many claim elements of Applicants' amended claims 12-15 and 25 are not found in the Linden and Langer reference or the Michlitsch reference.

The invention claimed in Applicants' amended claims 12-15 and 25 is an apparatus and method for closure of a physical anomaly in a vascular wall. Some of Applicants' claim elements of amended claims 12-15 and 25 that are not disclosed by the Linden and Langer reference or the Michlitsch reference include: a closure body, said closure body made of a shape memory polymer (SMP) foam, said shape memory polymer (SMP) foam having at least one hard segment and one soft segment wherein said hard segment is formed at a temperature above T_{trans} and said soft segment is formed at a temperature below T_{trans} , said shape memory polymer (SMP) foam being formed into a primary shape, compressed into a reduced secondary stable shape, then controllably actuated so that it recovers its primary shape, and a delivery device adapted to received said closure body made of a shape memory polymer (SMP) foam with said shape memory polymer (SMP) foam being compressed into said reduced secondary stable shape in said delivery device, said delivery device adapted to deploy said closure body into the physical anomaly in the vascular wall, wherein said shape

memory polymer (SMP) foam of said closure body in said reduced secondary stable shape is configured for positioning said closure body within the physical anomaly in the vascular wall, and wherein said shape memory polymer (SMP) foam is controllably actuated so that it recovers its primary shape with said primary shape configured to close said anomaly.

The provisions of M.P.E.P. Section 2142 require: (1) there must be some suggestion or motivation, either in the reference themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teaching, (2) there must be a reasonable expectation of success with the combined references system, and (3) that the prior art reference (or reference when combined) must teach or suggest all the claim limitations. The Linden and Langer reference and the Michlitsch reference and any combination of the three references fail to meet the three requirements of M.P.E.P. Section 2142. Accordingly the rejection of Applicant's claims 12-15 and 25 is not appropriate and the rejection should be withdrawn.

35 USC §103 Rejection – Linden et and Langer et al in View of Li

In the Office Action mailed February 14, 2007 on page 9, claims 5, 7, 27, and 29 were rejected under 35 USC §103(a) as being unpatentable over the Linden et reference (US Patent No. 5,634,936) and Langer et al reference (US Patent No. 6,388,043) in view of the Li reference (US 5,571,181).

Applicants have cancelled claims 27 and 29 and amended claim 5 and 7. Applicants believe the invention claimed in amended claims 5 and 7 is patentable over the Linden et, Langer et al, and Li references. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966) that are applied for establishing a background for determining obviousness under 35 USC §103 include "Ascertaining the differences between the prior art and the claims at issue." Differences between the Linden et, Langer et al, and Li

references and Applicants' claimed invention includes the fact that the many claim elements of Applicants' amended claims 5 and 7 are not found in the references.

The invention claimed in Applicants' amended claims 5 and 7 is an apparatus for closure of a physical anomaly in a vascular wall. Some of Applicants' claim elements of amended claims 5 and 7 that are not disclosed by the Linden et or the Langer et al or the Li references include: a closure body, said closure body made of a shape memory polymer (SMP) foam, said shape memory polymer (SMP) foam having at least one hard segment and one soft segment wherein said hard segment is formed at a temperature above T_{trans} and said soft segment is formed at a temperature below T_{trans} , said shape memory polymer (SMP) foam being formed into a primary shape, compressed into a reduced secondary stable shape, then controllably actuated so that it recovers its primary shape, and a delivery device adapted to received said closure body made of a shape memory polymer (SMP) foam with said shape memory polymer (SMP) foam being compressed into said reduced secondary stable shape in said delivery device, said delivery device adapted to deploy said closure body into the physical anomaly in the vascular wall, wherein said shape memory polymer (SMP) foam of said closure body in said reduced secondary stable shape is configured for positioning said closure body within the physical anomaly in the vascular wall, and wherein said shape memory polymer (SMP) foam is controllably actuated so that it recovers its primary shape with said primary shape configured to close said anomaly.

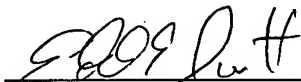
The provisions of M.P.E.P. Section 2142 require: (1) there must be some suggestion or motivation, either in the reference themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teaching, (2) there must be a reasonable expectation of

success with the combined references system, and (3) that the prior art reference (or reference when combined) must teach or suggest all the claim limitations. The Linden et al and Langer et al reference and the Li reference and any combination of the three references fail to meet the three requirements of M.P.E.P. Section 2142. Accordingly the rejection of Applicant's claims 5 and 7 is not appropriate and the rejection should be withdrawn.

SUMMARY

The undersigned respectfully submits that, in view of the foregoing amendments and the foregoing remarks, the rejections of the claims raised in the Office Action dated February 14, 2007 have been fully addressed and overcome, and the present application is believed to be in condition for allowance. It is respectfully requested that this application be reconsidered, that the claims be allowed, and that this case be passed to issue. If it is believed that a telephone conversation would expedite the prosecution of the present application, or clarify matters with regard to its allowance, the Examiner is invited to call the undersigned attorney at (925) 424-6897.

Respectfully submitted,



Eddie E. Scott
Attorney for Applicant
Registration No. 25,220
Tel. No. (925) 424-6897

Livermore, California

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